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*NOT ADMITTED IN DC

May 9, 2002

Dockets Management Branch
(HFA-09305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. 02N-0101: International Drug Scheduling;
Convention on Psychotropic Substances; Single Convention on
Narcotic Drugs ... Tramadol, 67 Fed. Reg. 17074 (Apr. 9,
2002)

Dear Sirs:

Johnson & Johnson holds the approved new drug application for tramadol, and has marketed this important analgesic in the United States for the past nine years. Following are our comments to the above-referenced Federal Register notice relating to the WHO questionnaire issued for tramadol and certain other medicines.

The subject Federal Register notice requests public comment on the WHO questionnaire, which asks questions about tramadol under four headings: 1) legitimate use of the substance; 2) abuse of the substance; 3) illicit activities involving the substance; and 4) impact of scheduling. It is our understanding that this questionnaire has been sent to the nations that are signatory to the conventions cited in the heading of the Federal Register

02N-0101

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notice. The responses to the questionnaire will be used by WHO in consideration of whether or how subject drugs should be scheduled under the conventions; WHO will use the data to make the medical and scientific decisions involved in scheduling and ultimately scheduling recommendations to the Commission on Narcotic Drugs ("CND"). These decisions will directly affect medical practice in this country. The questionnaire and the answers given to it are therefore important and deserve close attention.

The questionnaire is totally inadequate for its intended use, and it is likely that the responses it will elicit will be misleading. Looking at the questionnaire, an eminent expert in epidemiological research has said:

(T)he questionnaires are entirely inadequate to capture valid data and information about the nature and extent of substance abuse. The structure of the current questionnaires precludes collection of quantifiable data amenable to analysis. The format of the questionnaires encourages anecdotal responses, which will not provide the type of data required to assess the potential problems associated with abuse, or the extent of the problems.

See, Decl. of Frank L. Hurley, Ph.D., at ¶8, comment 1 submitted by PhRMA (Apr. 30, 2002).

The questionnaire, then, can rightly be considered as a threat to informed decision-making and a hazard to public health. If our government responds as the questionnaire invites, with anecdotal information, then the decisions made in the UN's scheduling process will not be properly founded, and may be a terrible mistake. Johnson & Johnson therefore encourages the responsible government officials to provide the WHO with data that can be used for decisions based on sound scientific data. The data are available to the United States government.

Johnson & Johnson has participated in the preparation of a current, full, methodologically correct review of the status of tramadol and its abuse history. This review is presented in a document entitled *Comprehensive Review of Abuse Risk for Tramadol*. It is submitted as an attachment to this comment. (We have also provided a copy of the review to the WHO secretariat, and requested that it be made available in a timely manner for the use of the experts working for WHO, and the expert committee that will consider the data for WHO.)

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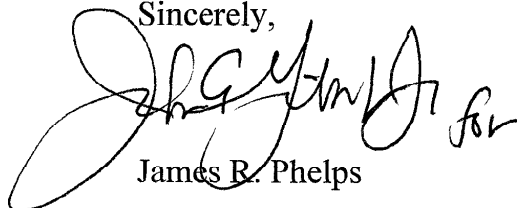
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In addition to this document, Johnson & Johnson asks our government to utilize for its response, the record of the drug abuse advisory committees (DAACs) that considered the uses and abuse profile of tramadol twice in the past decade, in 1994 and 1998. On both occasions, using the full body of available data, the panels of highly qualified experts recommended that tramadol not be scheduled under U.S. law. As a consequence, tramadol remains unscheduled in this country.

The data considered by these DAACs are especially valuable because of the intense, FDA-sanctioned program of postmarketing surveillance that has been used in this country for tramadol; this program of surveillance by experts has provided an unprecedented account of the abuse history of the subject drug, tramadol, since it was first marketed in the United States. We encourage our government to use these records in its response, and to provide copies of them to the WHO.

Johnson & Johnson wishes to emphasize that it is vital that our government, at this juncture, provide WHO with a full and accurate presentation relating to the uses and abuse history of tramadol. The scientific/medical judgments of WHO are final in the UN's scheduling process and binding on the CND on making a final scheduling decision. The WHO and its experts should have access to the unique and rich body of data that is available in this country. The interests of the citizens of this country can be served best by providing the data to WHO. Simply answering the wholly inadequate WHO questionnaire will not serve the interests of our citizens or good medicine.

Sincerely,

A handwritten signature in dark ink, appearing to read 'J.R. Phelps', is written over the typed name. The signature is fluid and cursive.

James R. Phelps

cc: Johnson & Johnson

JRP/JAG/map